

Kit SDS Cover Sheet MEGM Bullet Kit

Version 4.1

Revision Date 28.05.2024

Print Date 17.01.2025

Product Information

Product name : MEGM Bullet Kit

Material number : CC-3150

Components

MEBM Basal Medium	SDS attached
CC-4136 MEGM SingleQuot Kit Suppl&Growth Factors	
Hydrocortisone solution	SDS attached
GA-1000	SDS attached
Recombinant human insulin 0.5%	SDS attached
BPE High Protein - non specific	SDS attached
HEGF 10UG/ML FOR USE IN MEGM KIT	SDS attached

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

MEBM Basal Medium

Version 4.1

Revision Date 28.05.2024

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : MEBM Basal Medium

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

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5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

- | | | |
|--------------------------|---|--|
| Eye protection | : | Tightly fitting safety goggles |
| Hand protection | : | |
| Material | : | Nitrile rubber |
| Rate of permeability | : | > 480 min |
| Skin and body protection | : | Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required. |
| Respiratory protection | : | No personal respiratory protective equipment normally required. |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | | |
|--|---|-------------------|
| Physical state | : | liquid |
| Appearance | : | Aqueous solution |
| Colour | : | red |
| Odour | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flammability | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |

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Flash point	:	No data available
		No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	7,25 - 7,65
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

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SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

RID : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable

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TDG : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class(es) : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water hazard class (Germany) : WGK 1 slightly hazardous to water

15.2 Chemical safety assessment

not required

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SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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Hydrocortisone solution

Version 4.1

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : Hydrocortisone solution

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 2
Eye irritation, Category 2

H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

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Hazard statements	:	H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation.
Precautionary statements	:	<p>Prevention:</p> <p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/ eye protection/ face protection.</p> <p>Response:</p> <p>P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P337 + P313 If eye irritation persists: Get medical advice/ attention. P370 + P378 In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.</p>

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. REACH Registration Number	Classification	Concentration (% w/w)
Ethanol	64-17-5 200-578-6 603-002-00-5 01-2119457610-43-XX XX	Flam. Liq. 2; H225 Eye Irrit. 2; H319	>= 90 - <= 100
		specific concentration limit Eye Irrit. 2; H319 > 50 %	

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- | | | |
|-------------------------|---|---|
| If inhaled | : | Remove to fresh air.
If breathing is irregular or stopped, administer artificial respiration. |
| In case of skin contact | : | After contact with skin, wash immediately with plenty of soap and water.
Consult a physician. |
| In case of eye contact | : | In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Call a physician immediately. |
| If swallowed | : | If accidentally swallowed obtain immediate medical attention.
Clean mouth with water and drink afterwards plenty of water.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person. |

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|------------------------------|---|-----------------------------------|
| Suitable extinguishing media | : | Dry powder
Water spray
Foam |
|------------------------------|---|-----------------------------------|

5.2 Special hazards arising from the substance or mixture

- | | | |
|-------------------------------|---|---------------------|
| Hazardous combustion products | : | Carbon oxides (COx) |
|-------------------------------|---|---------------------|

5.3 Advice for firefighters

- | | | |
|---|---|--|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. |
| Further information | : | Use water spray to cool unopened containers. |

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- | | | |
|----------------------|---|--|
| Personal precautions | : | Use respirator when performing operations involving potential exposure to vapour of the product. |
|----------------------|---|--|

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6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms. Avoid contact with skin and eyes.

Advice on protection against fire and explosion : Highly flammable. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

Hygiene measures : Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep away from sources of ignition - No smoking. Keep containers tightly closed in a cool, well-ventilated place.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Countries not listed may have their own country specific values.

Occupational Exposure Limits

Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	500 ppm 960 mg/m ³	CH SUVA
		STEL	1 000 ppm 1 920 mg/m ³	CH SUVA

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Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanol	Consumers	Oral	Long-term systemic effects	87 mg/kg
	Consumers	Dermal	Long-term systemic effects	206 mg/kg
	Consumers	Inhalation	Long-term systemic effects	114 mg/m ³
	Workers	Inhalation	Long-term systemic effects	950 mg/m ³
	Workers	Dermal	Long-term systemic effects	343 mg/kg

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Ethanol	Fresh water	0,96 mg/l
	Soil	0,63 mg/kg
	Fresh water sediment	3,6 mg/kg
	Marine water	0,79 mg/l
	Sewage treatment plant	580 mg/l
	Marine sediment	2,9 mg/kg
	Oral	380 mg/kg

8.2 Exposure controls

Engineering measures

Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection

: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection

: In the case of vapour formation use a respirator with an approved filter.

Respirator with a vapour filter (EN 141)

Respirator with ABEK filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : colourless

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Odour	:	alcohol-like
Melting point/freezing point	:	-114,5 - -114 °C Information refers to the main component.
Initial boiling point and boiling range	:	78 °C Information refers to the main component.
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	15,0 %(V) Information refers to the main component.
Lower explosion limit / Lower flammability limit	:	3,5 %(V) Information refers to the main component.
Flash point	:	12 °C Information refers to the main component.
Auto-ignition temperature	:	No data available
Decomposition temperature Decomposition temperature	:	No data available
pH	:	No data available
Viscosity		
Viscosity, dynamic	:	1,17 - 1,2 mPa.s (20 °C)
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	0,79 g/cm ³ (20 °C)
Relative vapour density	:	No data available
Particle characteristics	:	No data available

9.2 Other information

No data available

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SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : Keep away from heat and sources of ignition.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Method: No information available.

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

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Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

The following toxicological data refer to:

Ethanol (CAS-No.: 64-17-5)

Acute toxicity

Acute oral toxicity : LD50 (Rat): > 5 000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 124,7 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 403

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation

Species: Rabbit
Result: Moderate eye irritation
Assessment: Mild eye irritation

Respiratory or skin sensitisation

Exposure routes: Dermal
Species: Mouse

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Result: not sensitizing

Germ cell mutagenicity

Genotoxicity in vitro

: Test Type: Ames test
Result: negative

: Test Type: gene mutation test
Species: mouse lymphoma cells
Result: negative

Repeated dose toxicity

Species: Rat, male and female
NOAEL: 1 730 mg/kg
LOAEL: 3 200 mg/kg
Application Route: Oral
Exposure time: 14 Weeks

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

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- Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
- Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- Product : Dispose of in accordance with local regulations. Contact waste disposal services.
- Contaminated packaging : Dispose of as unused product.

SECTION 14: Transport information

IATA

- 14.1 UN number : 1170
14.2 Proper shipping name : ETHANOL SOLUTION
14.3 Transport hazard class(es) : 3
14.4 Packing group : II
Labels : 3
14.5 Environmental hazards : no

IMDG

- 14.1 UN number : 1170
14.2 Proper shipping name : ETHANOL SOLUTION
14.3 Transport hazard class(es) : 3
14.4 Packing group : II
Labels : 3
EmS Number 1 : F-E
EmS Number 2 : S-D
14.5 Environmental hazards : Marine pollutant: no

ADR

- 14.1 UN number : 1170
14.2 Proper shipping name : ETHANOL SOLUTION
14.3 Transport hazard class(es) : 3
14.4 Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
14.5 Environmental hazards : no

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RID

14.1	UN number	: 1170
14.2	Proper shipping name	: ETHANOL SOLUTION
14.3	Transport hazard class(es)	: 3
14.4	Packing group	: II
	Classification Code	: F1
	Hazard Identification Number	: 33
	Labels	: 3
14.5	Environmental hazards	: no

DOT

14.1	UN number	: 1170
14.2	Proper shipping name	: Ethanol solutions
14.3	Transport hazard class(es)	: 3
14.4	Packing group	: II
	Labels	: 3
	Emergency Response Guidebook Number	: 127
14.5	Environmental hazards	: no

TDG

14.1	UN number	: 1170
14.2	Proper shipping name	: ETHANOL SOLUTION
14.3	Transport hazard class(es)	: 3
14.4	Packing group	: II
	Labels	: 3
14.5	Environmental hazards	: no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern : Not applicable for Authorisation (Article 59).

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

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Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

P5c	FLAMMABLE LIQUIDS	Quantity 1 5 000 t	Quantity 2 50 000 t
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Water hazard class (Germany) : WGK 1 slightly hazardous to water
Code Number: 96
Remarks: 03 2021

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Classification of the mixture:

Flam. Liq. 2 H225
Eye Irrit. 2 H319

Classification procedure:

Based on product data or assessment
Calculation method

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances

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and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

99 / EN

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : GA-1000

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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Signal word	:	Danger
Hazard statements	:	H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements	:	Prevention: P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P280 Wear protective gloves. P284 Wear respiratory protection. Response: P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Gentamicin, sulfate (salt)

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. REACH Registration Number	Classification	Concentration (% w/w)
Gentamicin, sulfate (salt)	1405-41-0 215-778-9	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 3 - < 5

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : Move to fresh air.
Call a physician or poison control centre immediately.
If unconscious, place in recovery position and seek medical advice.
Keep respiratory tract clear.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
Wash clothing before reuse.
Get medical attention if irritation develops and persists.

After contact with skin, wash immediately with plenty of soap and water.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If eye irritation persists, consult a specialist.

Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Allergic appearance
sensitising effects

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

Treat symptomatically.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Not combustible.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Water spray

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Heating or fire can release toxic gas.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Further information : Use a water spray to cool fully closed containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use respirator when performing operations involving potential exposure to vapour of the product.
Refer to protective measures listed in sections 7 and 8.
Use personal protective equipment.
Ensure adequate ventilation.
Use respirator when performing operations involving potential exposure to vapour of the product.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

For disposal considerations see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of aerosol.
Avoid exposure - obtain special instructions before use.
Do not breathe vapours/dust.
Avoid contact with skin and eyes.
Smoking, eating and drinking should be prohibited in the application area.
For personal protection see section 8.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.

Advice on protection against fire and explosion : Stable under normal conditions.

Normal measures for preventive fire protection.

Hygiene measures : Wash hands before breaks and at the end of workday. Avoid contact with skin, eyes and clothing.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep frozen or refrigerated.

Observe label precautions. Keep container tightly closed. Keep in a well-ventilated place. To maintain product quality, do not store in heat or direct sunlight.

Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Use only in area provided with appropriate exhaust ventilation.

Personal protective equipment

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Eye protection	:	Safety glasses
Hand protection	:	
Material	:	Nitrile rubber
Remarks	:	Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact). Impervious gloves Break through time : > 480 min The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. Impervious clothing
Respiratory protection	:	In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit. Respirator with ABEK filter. Respirator with combination filter for vapour/particulate (EN 141) Respirator with a vapour filter (EN 141)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	light yellow
Odour	:	odourless
Melting point/freezing point	:	0 °C
Initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Does not sustain combustion.

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Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	soluble
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity : Acute toxicity estimate: Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

Repeated dose toxicity

Remarks: No data available

Aspiration toxicity

No aspiration toxicity classification

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11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Neurological effects

Remarks: No data available

Further information

Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

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(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- Product : Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.
Do not dispose of waste into sewer.
- Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

SECTION 14: Transport information

IATA Not dangerous goods

- 14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG Not dangerous goods

- 14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

- 14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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RID : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class(es)** : Not applicable
 14.4 **Packing group** : Not applicable
 14.5 **Environmental hazards** : no

DOT : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class(es)** : Not applicable
 14.4 **Packing group** : Not applicable

TDG : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class(es)** : Not applicable
 14.4 **Packing group** : Not applicable
 14.5 **Environmental hazards** : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

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Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Water hazard class (Germany) : WGK 1 slightly hazardous to water

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Classification of the mixture:

Resp. Sens. 1 H334

Skin Sens. 1 H317

Classification procedure:

Calculation method

Calculation method

Full text of H-Statements

H317

: May cause an allergic skin reaction.

H334

: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Full text of other abbreviations

Resp. Sens.

: Respiratory sensitisation

Skin Sens.

: Skin sensitisation

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT -

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Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Other information : This Safety Data Sheet is a generic European Safety Data Sheet and therefore does not contain all specific information for each European country.

Date format : dd.mm.yyyy

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : Recombinant human insulin 0.5%

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Insulin: may cause hypoglycaemia.

Insulin is inactivated in the gastro-intestinal tract when ingested.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Wash with water and soap as a precaution.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician.
- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Heating or fire can release toxic gas.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Further information : Use a water spray to cool fully closed containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.
Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Dispose of in accordance with local regulations.

Use neutralizing agents.
Neutralize with chalk, alkali solution or ammonia.
Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

For disposal considerations see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : No special precautions required.
For personal protection see section 8.
- Advice on protection against fire and explosion : No special precautions required.

Normal measures for preventive fire protection.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep container tightly closed. Keep in a well-ventilated place.
To maintain product quality, do not store in heat or direct sunlight.
- Advice on common storage : No special restrictions on storage with other products.
- Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

- Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Use only in area provided with appropriate exhaust ventilation.

Personal protective equipment

- Eye protection : Safety glasses
- Hand protection
Remarks : Wear protective gloves. Break through time : > 480 min
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Lightweight protective clothing
- Respiratory protection : No personal respiratory protective equipment normally

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required.
In the case of vapour formation use a respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: liquid
Appearance	: Aqueous solution
Colour	: colourless
Odour	: odourless
Melting point/freezing point	: No data available
Boiling point/boiling range	: No data available
Flammability	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: Water
Auto-ignition temperature	: No data available
Decomposition temperature Decomposition temperature	: No data available
pH	: 2 - 4
Viscosity Viscosity, kinematic	: No data available
Solubility(ies) Water solubility	: completely soluble
Partition coefficient: n-octanol/water	: No data available
Vapour pressure	: No data available
Relative density	: No data available
Density	: No data available
Relative vapour density	: No data available

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Particle characteristics : No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Assessment: No skin irritation

Serious eye damage/eye irritation

Assessment: No eye irritation

Respiratory or skin sensitisation

Remarks: No data available

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Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

Aspiration toxicity

No aspiration toxicity classification

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: Insulin: may cause hypoglycaemia.
Insulin is inactivated in the gastro-intestinal tract when ingested.
May cause central nervous system depression.
May induce sweating, pallor or visual disturbances.

Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

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12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Solutions with low pH-value must be neutralized before discharge.
Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

RID : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable

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TDG	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class(es)	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water hazard class (Germany) : nwg not water endangering

15.2 Chemical safety assessment

not required

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SECTION 16: Other information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Other information : This Safety Data Sheet is a generic European Safety Data Sheet and therefore does not contain all specific information for each European country.

Date format : dd.mm.yyyy

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Version 4.1

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Print Date 17.01.2025

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : HEGF 10UG/ML FOR USE IN MEGM KIT

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

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5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

Eye protection	:	Tightly fitting safety goggles
Hand protection	:	
Material	:	Nitrile rubber
Rate of permeability	:	> 480 min
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.
Respiratory protection	:	No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	No data available
Odour	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

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Flash point	:	No data available
		No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

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SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

RID : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable

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TDG : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water hazard class (Germany) : WGK 1 slightly hazardous to water

15.2 Chemical safety assessment

not required

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SECTION 16: Other information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : BPE High Protein - non specific

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : Sodium oxides

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Carbon oxides (COx)
Hydrogen chloride (HCl)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

Eye protection	:	Tightly fitting safety goggles
Hand protection	:	
Material	:	Nitrile rubber
Rate of permeability	:	> 480 min
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.
Respiratory protection	:	No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	No data available
Odour	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

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Flash point	:	No data available
		No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

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SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

RID : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable

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TDG : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class(es) : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water hazard class (Germany) : nwg not water endangering

15.2 Chemical safety assessment

not required

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SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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